Medical Science

Effectiveness of the insulin pump on type 1 diabetes in controlling HbA1C in Riyadh, Saudi Arabia

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ABSTRACT

Background: Type 1 diabetes is one of the most common spreading diseases in Saudi Arabia. In addition, HbA1C is the gold standard measure for diabetes glycemic control, so the aim is to reduce the HbA1C to minimize the microvascular and macrovascular complications of diabetes. *Aim:* To measure the use of therapeutic insulin pumps for type 1 diabetic patients and asses the HbA1C level before and after the insulin pump insertion. *Methods:* A cross-sectional study was done to type 1 diabetic (T1D) on a Medtronic insulin pump with a sensor (basal vs. IQ) in KSH and a virtual clinic. *Conclusion:* Insulin pump therapy considers an ideal solution for the reduction in HbA1C, increased patients' treatment satisfaction, and maintaining glycemic control compared to injectable insulin.

Keywords: Insulin pump – Type 1 Diabetes – HbA1C control

1. INTRODUCTION

Diabetes mellitus type 1 (T1D) is known as insulin-dependent diabetes. Globally the incident was estimated to be 234,710 (Green et al., 2021) the incident rate increased by about 3%-4% yearly, with younger onset than before. The Kingdom of Saudi Arabia (KSA) considered the highest incidence of T1D among the Middle Eastern and North African regions, accounting for one-quarter of the cases (Robert et al., 2018). According to a screening project on T1D in KSA conducted from 2001 to 2007, the prevalence rate of children and adolescents with T1D accounted for 109.5 per 100,000. Additionally, it was lowest in the eastern province (48 per 100,000) and highest in the central region (126 per 100,000) (Al-Herbish et al., 2008).

Literature review
Demographic characteristics of pump users
A study in New Zealand was done to identify patients with T1D; it showed that funded pump use among 13,727 patients increased to 9.3%; however, demographic characteristics and region are considered variable factors in demanding the pump. For example, another study found that pump use was significantly higher in females than for males, with an odds ratio (OR) of 2.0

DISCOVERY

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concerning those aged less than 20 years old in some regions (McKergow et al., 2017).

According to American diabetes, having HbA1C of less than 7% will reduce microvascular complications for both types 1 and 2 when achieved in the early stage of the disease. Therefore, they suggested that the more lowering HbA1C from 7% to 6%, the more reduction in microvascular complications. The American Diabetes Association recommend a target value for HbA1c in proportion to age group to be <8.5% (<69 mmol/mol) at age <6 years, <8 (<64 mmol/mol) % for the age group 6 to 12 years, <7.5% (<58 mmol/mol) between 13 to 18 years and <7% (<53 mmol/mol) in adults (Standards of Medical Care in Diabetes, 2012).

Effectiveness of pump on HBA1C level
A Trial for Diabetes Control and Complications showed that amending HbA1C by 1% for people with T1D reduces microvascular complications by 25%. Microvascular complications include Retinopathy, Neuropathy, and diabetic nephropathy (Stratton et al., 2000). To reach the goal according to American Diabetes Association showed another study in Denmark studied 3909 adults complaining of T1D. The distribution of patients treated with insulin pumps in the eight regional hospitals significantly differed from 12.0% to 31.1%. Overall, insulin pump users had a marked lower HbA1C level compared to multiple dose injection treated patients, 7.6% versus 8.0% (Kampmann et al., 2018).

Eligibility criteria for insulin pump insertion
A study conducted in Sweden to address the indications of insulin pump as a treatment for T1D showed the frequent usage of insulin pump therapy in younger individuals with early-onset diabetes and problematic glycemic control. In addition, the use of insulin pumps was concerned with lower HbA1C levels among insulin pump users, except for those who started insulin pumps due to high HbA1C (Jendle et al., 2016).

Studies on the insulin pump in KSA in adult age group
A prospective study conducted on 47 T1D patients between the ages of 17-24 attending the Insulin Pump Clinic at Prince Sultan Military Medical City (PSMMC) in Riyadh, Saudi Arabia; shows that there was a significant positive difference in HbA1C levels compared to baseline after six months of treatment. In addition, the frequency incidence of hyper/hypoglycemia attacks significantly declined (Al Hayek et al., 2015).

A case-control study was conducted in Saudi Arabia among 200 adult T1D patients who applied for insulin pump therapy, and alternative insulin injection therapy results showed that insulin pump, compared to insulin injection, was associated with more satisfactory glycemic control. However, the hypoglycemic episodes were minimally reported per week, while the diabetic-ketoacidosis (DKA) was reported annually in pump therapy compared to the injection therapy patients (Almogbel, 2020).

A retrospective study among 118 Saudi patients with T1D in King Abdulaziz Medical City-Saudi Arabia to detect insulin pump therapy complications concluded that a high prevalence of T1D adult patients experiencing device malfunction error during therapy; This may show the insignificant improvement in the glycemic control among the targeted patients (Al-Saleh et al., 2020).

Barriers or causes of not using insulin pump
A recent study in the USA (Pauley et al., 2021) represent that despite the benefits associated with the use of diabetes insulin pump, ongoing barriers to technology adoption are well recognized and include common themes:
Physical burden concerns include a continual attachment to a device and hindrance in physical activity, cosmetic impact, and skin injury.
Patient attitudes toward the technology and expectations
Lack of resources for healthcare providers and negative provider attitudes towards technology
Lack of access related to incomplete coverage and high cost.
The possibility of racial and ethnic variance in device use is related to provider and patient biases about device use.

Psychosocial barriers
Psychologists and certified diabetes care and education specialist (CDCES) specialize in treating people with T1D (Berget et al., 2019). Summarize the obstacles that may keep diabetic patients from trying insulin pumps as follow:
Wearability: Using an insulin pump means consistently wearing the device.
Limitation: Lack of flexibility as the patient may feel stuck.
Skin Irritation: some the patient may develop reactive skin allergy.
Burden: T1D management takes time, and Insulin pumps can reduce the burden of diabetes, but some people fear the opposite.

The research was conducted in Irish among 21 interviews to explore why uptake was lower in this country. The research results if the health service structure was insufficient, the quality of care was not standardized, and capacity was poor. Moreover, that insulin pump therapy relied more on the patient's desire and knowledge (Pauley et al., 2021).

The insulin pump successfully decreases the HbA1C reading

A researcher in Turkey took 167 diabetic children on insulin pump therapy and measured HbA1C, BMI, lipid profile, and albumin/creatinine ratio one year before and after insulin pump insertion. The HbA1C values were significantly lower at the individual visits and on average compared to the one-year average before the insulin infusion pump ($P<0,001$). In contrast, Body mass index values were significantly higher than the one-year average before the insulin infusion pump ($P<0.001$). In addition, there was an insignificant difference in LDL, triglyceride, and microalbumin/creatinine ratio before and after the infusion pump.

Another case-control study compared 216 diabetic patients (children and adults) to measure HbA1C, BMI, age, and gender for two years. Results show that it took the insulin pump group 6-12 months to improve the HbA1C levels compared to the multiple injection groups. Meanwhile, the occurrence of ketoacidosis attack was higher in the insulin pump group compared with the multiple injection groups (2.8 vs. 0.5/100 person-year) (Brorsson et al., 2015).

Rational

Insulin pumps have a strong impact on improving diabetic type 1 HBA1C levels and reducing early complications.

Objectives

To identify the characteristics of T1D patients using therapeutic insulin pump in King Salman Hospital and virtual clinic, Riyadh, Saudi Arabia.

To study the impact of using insulin pump therapy in T1D patients in glycemic control and HbA1C reduction

To compare HbA1C measures before and after inserting the therapeutic insulin pump in T1D patients.

2. METHODS

Study design

Quantitative Analytical cross-sectional study

Target population

All T1D on Medtronic insulin pump with sensor (basal vs. IQ) in KSH and virtual clinic

Study settings

King Salman hospital virtual clinic in Riyadh – Saudi Arabia

Study Duration

April 2022 to June 2022.

Inclusion criteria

Under KSH and virtual clinic

Saudi, Non-Saudi with Saudi mother

Eligible access and follow-up in MOH hospital

T1D on insulin pump

HBA1C readings are available 3-9 months or a year before and after pump insertion

Exclusion criteria

Non-Saudi

No data was recorded in MOH hospitals before insulin pump insertion

Discontinue pump because DKA after pump insertion during the first year

Discontinue pump because no supply from the hospital

Discontinue pump because any medical issue after use example: allergy to the needle tape

Start on pump for less than a year

Sample size

Total number 64 after exclusion criteria

Variables

Dependent V: HBA1C decreased by at least 1%.

Independent V: Age, Gender, Duration of insulin pump therapy.

When to say Effective or controlled: if HBA1C decreased by at least 1%

Average lab results calculation: Average of 2 -3 reading from (before and after) pump insertion and divided by the number of readings.

Study Technique

Medtronic basal IQ is used to prevent hypoglycemia if blood glucose is lower than 80mg/dl. Medtronic control IQ is used to prevent hypoglycemia and hyperglycemia and keep blood glucose levels between 70-180 mg/dl. The aim is to maintain the blood sugars between 112.5-160 mg/dl and keep the insulin pump users in the default setting. If the reading is above 180 mg/dl, the insulin pump gives a correction bolus. If it is going to be above 160 mg/dl, it will increase the basal rate. On the other hand, if glucose levels will drop below 112.5 mg/dl, it will decrease the amount of basal insulin, and if the readings reach below 70mg/dl, it will turn off the basal insulin.

Data collection method and tool

The data will be collected from this database through the primary investigator from the extracting sheet from a secondary database belonging to the MOH in king Salman hospital, Insulin Pump Program, which started in 2014 with 500 pumps all over the Kingdom. By using extracting tool form, this tool contains national identity document, demographic (date of birth, gender), date of diagnosis, HBA1C readings (average of 3 readings before pump insertion and after pump insertion for a year or more), age at diagnosis, age at insulin pump insertion, BMI, causes of discontinue pump use. Virtual clinic patients where phones called HBA1C: from the patient's record within 3-9 months or a year before and after the pump insertion.

Ethical consideration

All information and data will be confidentially used only for this research purpose, and institutional review board approval was taken [IRB Registration Number with King Saud Medical City Riyadh, KSA: H-01-R-053].

Budget & Fund

The study has not received any external funding.

Data analysis

The data will be analyzed using SPSS version 23. The data will be extracted from an Excel sheet and then entered into SPSS. Continuous variables were expressed as mean ± standard deviation, and categorical variables were expressed as percentages. Variables were analyzed through a T-test and categorical variables through a Chi-square test. If P-value < 0.05 was considered statistically significant for categorical variables, will be presented as frequency and percentage, and continuous variables will be presented as mean and SD. We did a normality test (dependent variable: average HbA1C after pump insertion, factor: duration of DM in groups). The result was not significant, so it's normally distributed. Our analysis will use a parametric test. We will use paired t-test and McNamara test for the categorical data and the Wilcoxen test for continuous data. P-value will be two-tailed, and less than 0.05 will be considered significant.

3. RESULT

The study sample size is 64 total diabetic patients on the insulin pump in KSH in Riyadh. The demographics and characteristics of the sample are illustrated in table 1. Of the study population, 67 % were female, the median and mean age was 25 years, the age group 29 to 38 years represented 33%, below 18 age group represented 22% of the population, about 6% from 19 to 28 years old, and

only 1.6% represent above 39 years old. Regarding the duration of DM, the mean was 13 years. About 58 % of the sample has diabetes duration between 8 to 16 years, and 23% have less than eight years duration of DM.

Table 1 The demographic and characteristic of the patients on insulin pump

			Number or mean ±SD	%
	Gender	female	21	32.8
		male	43	67.2
	Age		24.58 ± 8.6	
		<18	14	21.9
		18-28	28	6.4
		>28-38	21	32.8
		>38	1	1.6
	Duration of DM for all sample		12.80 ± 6.3	
	Groups duration (years)	<8	15	23.4
		8-16	37	57.8
		>16-25	9	14.1
		>25	3	4.7

Table 2 shows the average duration of the pump is 5.8 ± 3 years. Most of the population 58% have been on pump from 5 to 9 years, followed by 37 % on pump for less than five years and about 3%, 1.6% on pump for more than 15 years and from 10 to 14 years (Figure 1).

Table 2 Duration of pump inserted in T1D patients.

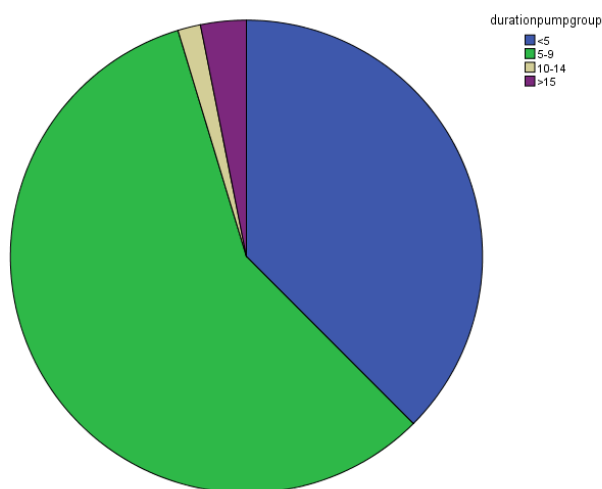|	mean	SD
Duration of pump	5.79	3.027
	Frequency	%
<5	24	37.5
5-10	37	57.8
>10-15	1	1.6
>15	2	3.1

Figure 1 The duration pump group.

Table 3 shows the HbA1C level before and after insulin pump insertion in T1D study population in KSH. The average HbA1C before is 9.5 % ± 2; on the other hand, the average HbA1C after is 8.2 % ± 1.3. HbA1C average is decreased by 1.4 with a p-value <0.001. Before pump insertion, the majority, 59 % of the population, has HbA1C above 9 and 14 % of the population has HbA1C less

than 9 to 8 and less than 7 (Figure 2). Whereas after pump insertion only 23% has HbA1C above 9 (which decreased by 36% than before pump insertion) and about 33 % has HbA1C less than 9 to 8, and 20 % has HbA1C less than 8 to 7. The HbA1C less than 7 were represented 14% before the pump, and then it increased to 23 % after pump insertion. Figure 3 show the decrease in average HbA1C after pump insertion in both male and female.

Table 3 Compare HbA1C level before and after insulin pump insertion in T1D patients in 2022.

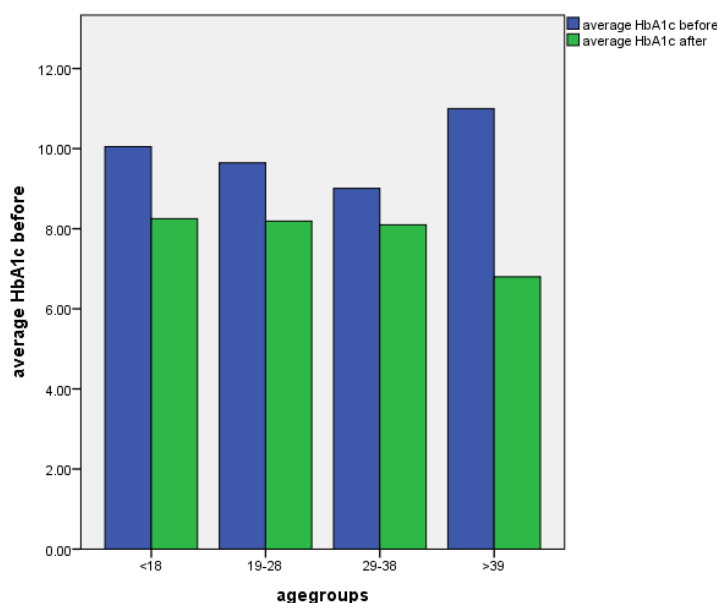|	Before		After		P-value
	mean	SD	mean	SD	
average HbA1C	9.54	1.99	8.15	1.25	.000
	Frequency	%	Frequency	%	
<7	9	14.1	15	23.4	
7-7.9	8	12.5	13	20.3	
8-8.9	9	14.1	21	32.8	
>9	38	59.4	15	23.4	

Figure 2 This figure shows the decrease in average HbA1C after pump insertion in all age groups.

4. DISCUSSION

The key finding from this study was how much the insulin pump is effectively decreasing the HbA1C to reach the ideal target for T1D. Our study shows a significant decrease in HbA1C value after insertion of the insulin pump by an average of (1.39 mmol/mol). This reduction is compatible for the all-age group and both male and female gender within the first year of the insulin pump insertion. By setting our results side by side with the national published study; We found a case-control study comparing insulin injection and insulin pumps among diabetic patients found a significant difference (P-value 0.001) in decreasing HbA1C to 7 and less after six months of use of the pump compared to insulin injection (Robert et al., 2018). Moreover, a study conducted among T1D patients used insulin pump therapy for ten months duration found a significant reduction in HbA1C, increased patients' treatment satisfaction, and maintained glycemic control (Al Hayek et al., 2015). In addition, a retrospective study has proved that the pump overall is effective in decreasing the HbA1C level in all participants (p < 0.001), but HbA1C remains suboptimally improved in the glycemic control with a comment on issues on adherence and insulin pump malfunctions should be investigated further (Al-Saleh et al., 2020). This makes achieving the ideal glycemic control among Saudis with diabetes remain a challenge for both the patient and the entire healthcare team. On the other hand, an observational cross-sectional study conducted between 2008

and 2014 among eighty patients treated with insulin pump therapy concluded that a remarkably improved diabetes control and quality of life in T1D and decreased the incidence of DKA and rate of hospital admission with the warning of the necessity careful follow-up provided to the patients by diabetes educators and dietitians (Alqambar, 2018).
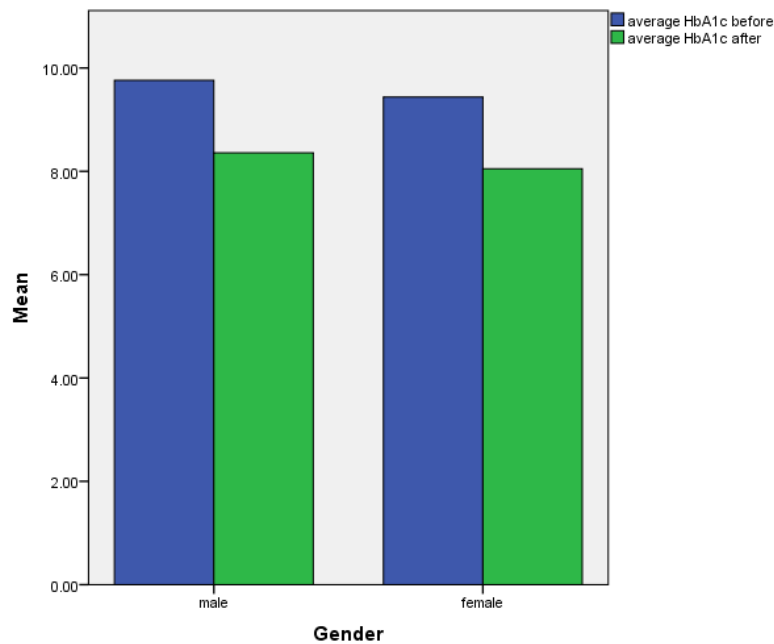

Figure 3 This figure shows the decrease in average HbA1C after pump insertion in relation to gender.

This study compared HbA1C before and after pump insertion, giving a significant p-value that the pump is effective in decreasing HbA1C among the targeted group. This is compatible with a study in Sweden among 272 diabetic patients on insulin pump therapy and 2,437 patients on multiple daily insulin injections, representing patients with high HbA1c levels have a greater probability of improved HbA1c after initiating pump therapy. Although the effects remain relatively low, for poorly controlled patients (Clements et al., 2015). Moreover, A meta-analysis study of anonymized 160 patients diagnosed with T1D who commenced insulin pump therapy at Imperial College Healthcare NHS between 1980 and 2018 defined glycemic tracking as statistically insignificant (P<.05) of HbA1C of any two years before and after the onset of insulin pump therapy but predominantly the significant difference of HbA1C reduction was markedly noted between the year immediately before and after the commencement of the treatment (P< .0001) (Johnson et al., 2020).

5. CONCLUSION
Insulin pump therapy considers an ideal solution for the reduction in HbA1C, increased patients' treatment satisfaction, and maintaining glycemic control compared to injectable insulin.

Limitation
Unavailability of another study to understand the causes, and obstacles to reaching ideal HbA1C.

Recommendation
To conduct several studies comparing different pump types (basal vs IQ).

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